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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,901	09/27/2001	Mark S. Roby	2788	3223

7590 10/01/2003

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EXAMINER	
MICHENER, JENNIFER KOLB	

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/964,901	ROBY ET AL.	
	Examiner	Art Unit	
	Jennifer Kolb Michener	1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) *16-29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) ~~Paper No(s).~~ 11/27/02.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper of 8/15/2003 is acknowledged. The traversal is on the ground(s) that separate classification is not conclusive proof of divisibility and that there would not be serious burden on examiner due to the coextensive search of the three groups. This is not found persuasive. Separate classification was not the only basis of the restriction requirement. Examiner notes that the three sets of claims contain divergent subject matter, have a different status in the art, and require different searches. In Applicant's disclosure, inventions I and II are disclosed as separate and distinct embodiment's of Applicant's invention. These inventions are directed to different subject matter. Invention I requires the use of a siloxane material with a suitable viscosity followed by effective polymerization of said material with a siliconization material. Whereas, Invention II does not require these limitations, but does requires that the two materials not be covalently linked and that the second material crosslink, locking the siloxane therein in an interpenetrating network. Regarding the product claim, different processes may be used to make such a product, as was outlined in the previous action.

The art used for each of these inventions would be different, the searches are different, and different issues will arise during prosecution relative to each different invention.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The disclosure is objected to because of the following informalities: the use of trademarks such as "Syl-Off" and "Medical Fluid" has been noted in this application. They should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2, 5-7, and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelkey (5,911,711).

Pelkey teaches a method of coating a needle, which inherently has a surface, by applying a coating mixture to the surface of the needle. The coating mixture of Pelkey contains a polydialkylsiloxane, with a viscosity of 12,500 cs (col. 3, line 15) and one other siliconization material (col. 3, line 13), known by MDX 4-4159. The mixture of Pelkey is then cured (col. 3, line 45), as required by claim 1.

Based on the density of polydimethylsiloxane, it appears that the viscosity of 12,500 cs would meet the limitation of "at least about 10,000 cp", as required by Applicant. Additionally, because the polydialkylsiloxane is polydimethylsiloxane, as required later in claim 4, and the siliconization material is the same as one described in the instant specification and in later dependent claims, the molecular weights will inherently provide a viscosity of the coating mixture of at least 10,000 cp, as required by Applicant.

While Pelkey's coating method is specifically directed to "hypodermic needles", Examiner notes that hypodermic needles may be used during the course of surgery. Additionally, it is Examiner's position that Pelkey's method of lubricating hypodermic needles to decrease the penetration force would also be useful in needles used in surgery. It would have been obvious to one of ordinary skill in the art to use Pelkey's method of lubricating hypodermic needles on surgical needles to decrease the force necessary to pierce flesh during surgery, rendering surgery less tiring for the surgeon and less painful for the patient.

Regarding claim 2, Pelkey teaches the use of the polydialkylsiloxane in a solvent and the siliconization material (MDX) in a solvent (col. 3, lines 12 and 17).

Regarding claims 5-7, the siliconization material of Pelkey, MDX 4-4159, is dimethoxysilyldimethylaminopropyl silicone and another dimethylsiloxane copolymerizable therewith, as defined by Pelkey and as known in the art. These compounds qualify as an "aminoalkyl siloxane" and a "polydimethylsiloxane having amino and alkoxy functional groups". The siliconization material of Pelkey is supplied in a mixture of solvents, including isopropyl alcohol (col. 3, line 13).

Needles are dipped, as required by claim 9 (col. 3, line 21).

Pelkey teaches that, after the mixture above is applied to the needles, they are stored to become at least partially cured and that the cure may be allowed to occur under ambient conditions, but that the rate of cure may be accelerated by oven warming until sufficiently cured (col. 3, lines 29 and 45-55). This two-step curing method involving a first-step of storing, which would evaporate the solvent (col. 4, line 7), and a second step of oven curing reads on Applicant's two-step curing method outlined in claims 10-13.

In the first step of storing, Pelkey does not specify conditions. In the absence of a showing of criticality and in light of Pelkey's disclosure of ambient conditions being suitable for the coated substrates, it is Examiner's position that it would have been obvious to an ordinary artisan to store Pelkey's coated needles under ambient conditions, which fall within Applicant's temperature and relative humidity ranges claimed in claims 10-13. For example, today in Washington DC it is currently 77 °F with a relative humidity of 55%, lying within the ranges claimed by Applicant. Regarding the length of time useful for this storing step which partially cures the coating in the method of Pelkey, it is Examiner's position that selection of an optimal time would have been within the skill of an ordinary artisan depending on the amount of cure desired prior to the oven stoving stage of the curing operation.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding the stoving operation, Pelkey teaches the use of temperature up to 100 °C or higher unless the hub is thermoplastic (col. 3, lines 45-55). Since surgical needles do not have hubs, this teaching allows temperatures of over 100 °C, overlapping the ranges claimed by Applicant.

Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Pelkey's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

Pelkey teaches that the oven curing occurs until the coating is sufficiently cured, but does not teach a time for such sufficient curing. However, it is Examiner's position that optimizing cure time for a given temperature would have been within the skill of an ordinary artisan desiring to achieve a "sufficient curing" for those reasons outlined above.

The selection of heating times and temperatures would have been selected and optimized by one of ordinary skill in the art for those reasons outlined above, regarding claim 14.

7. Claims 3-4, 8, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pelkey in view of Mathisen et al. (5,456,948).

Pelkey teaches that which is disclosed above regarding the application of a polydimethylsiloxane and siliconization material in solvents. Particularly, Pelkey

teaches the application of polydialkylsiloxane in a substantially non-polar volatile and inert solvent (col. 3, line 29), but fails to specifically teach the use of hexane.
Mathisen teaches a method of lubricating medical articles, such as surgical needles, with a solution of polydialkylsiloxane in hexane (col. 3, line 10, col. 4, line 14, col. 4, line 42; examples). Hexane is a hydrocarbon of 5-10 carbon atoms, as required by claim 3. It is also an example of a substantially nonpolar, volatile, inert solvent, as called for by Pelkey. Since Pelkey teaches the use of a nonpolar, volatile, inert solvent for use with polydialkylsiloxane for coating needles and Mathisen teaches the use of hexane as such a solvent for polydialkylsiloxane, Mathisen would have reasonably suggested the use of hexane in the method of Pelkey. It would have been obvious to one of ordinary skill in the art to use the teachings of Mathisen in the method of Pelkey with the expectation of successful results since Mathisen teaches the suitability of hexane with polydialkylsiloxane for coating needles.
Pelkey teaches that the polydialkylsiloxane of his invention is polydimethylsiloxane, as also required by claim 4 (col. 3, line 15).

The limitations of claim 8 are discussed in regards to claim 3-4 in this rejection and claims 5-7 of the Pelkey rejection, taken together.

Regarding claim 15, Pelkey teaches the use of the first siloxane and the siliconization material (MDX) in a ratio of 2:4, or 1:2, lying within the range claimed by Applicant (col. 3, lines 11 and 14).

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Prasad teaches a method of lubricating surgical or hypodermic needles with a solution of MDX 4-4159 and polydimethylsiloxane and curing. Granger (EP 0 494 648 A2) is cited for teaching a needle coating of MDX 4-4159 in hexane cured by room temperature evaporation conditions followed by heating using appropriate temperature and humidity conditions. Heinz teaches coating a syringe with a 2-component lubricant of specific viscosity (see claims). Walther teaches coating a surgical needle with MDX in solution and Syl-Off in solution (as outlined in the instant specification) and curing.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
September 24, 2003